DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#220

APR 3 2003

Re: Prevnar
Docket No.: 00E-1403

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,360,897, filed by University of Rochester through American Home Products, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Prevnar, the human biological product claimed by the patent.

The total length of the regulatory review period for Prevnar is 1,910 days. Of this time, 1,648 days occurred during the testing phase and 262 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: November 27, 1994.

   The applicant claims November 25, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 27, 1994, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: June 1, 1999.

   FDA has verified the applicant's claim that the product license application (PLA) for Prevnar (PLA 99-0279) was initially submitted on June 1, 1999.

3. The date the application was approved: February 17, 2000.

   FDA has verified the applicant's claim that PLA 99-0279 was approved on February 17, 2000.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Estelle J. Tsevdos
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